

REMARKS

Claims 1-37 are pending in the subject application. Applicants respectfully request reconsideration of the subject application in view of the following remarks.

Rejection Under the Judicially Created Doctrine of Obvious-Type Double Patenting

On page 2 of the Office Action claims 1-37 of the subject application stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 9, compounds 1 and 2, claims 10-23 of U.S. Patent No. 6,235,764 ("the '764 patent"). The Examiner further states that the alleged conflicting claims are not identical, they are not patentably distinct from each other. The Examiner notes that the instant claims are drawn to various salts of 3-(4-bromo-2,6-difluoro-benzyloxy-5-[3-(4-pyrrolidin-1-yl)-butyl]-ureido]-isothiazole-4-carboxylic acid amide, pharmaceutical compositions and method of using same. The Examiner states that the difference between the claimed salts and the reference is that the instant claims are to specific salts of the compounds that are not claimed. The Examiner points applicants' to claim 10 of the reference and the list of various salts that can be made, citing, column 11, lines 38-50. The Examiner concludes that one of ordinary skill in the art would be motivated to make additional salt forms of this known compounds with the specific suggestion and teaching that the reference provides that the claimed salt form can be made. Applicants respectfully traverse the Examiner's rejection of the claims 1-37 of the instant application over the '764 patent for the following reasons.

"Obviousness-type" double patenting is "judicially created and prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent." *In re Lonardo*, 119 F.3d 960, 965 43 USPQ.2d 1262, 1266 (Fed. Cir. 1997). The proper question in an obviousness-type double patenting inquiry is whether the claims at issue would have been obvious to one of ordinary skill in the art over the subject matter of the claims in the first patent. *See, e.g., In re Kaplan*, 789 F.2d 1574, 1579-80, 229 USPQ 678, 682 (Fed.Cir.1986); *In re Longi*, 759 F.2d 887, 893, 225 USPQ 645, 648 (Fed.Cir.1985). "In considering the question, the patent disclosure may not be used as prior art." *In re Vogel*, 57 C.C.P.A. 920, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970).

In certain instances the patent disclosure may be used as a dictionary to learn the meaning of terms in a claim. *Id.* at 441.

Applicants respectfully submit that the claims of the instant application are not an obvious variation of the issued claims of the '764 patent. Applicants respectfully submit that that claims of the '764 patent claim the mesylate and hydrochloride salt of the 3-(4-bromo-2,6-difluoro-benzyloxy-5-[3-(4-pyrrolidin-1-yl)-butyl]-ureido]-isothiazole-4-carboxylic acid amide. The claims of the present invention are directed to a distinct set of salts from that of the '764 patent. The Examiner asserts that one of ordinary skill in the art would be "motivated to make additional salt forms of this known compounds with the specific suggestion and teaching that the reference provides that the claimed salt form can be made."

To support this assertion the Examiner points to claim 10 of the reference and the list of various salts that can be made, citing, column 11, lines 38-50.

Applicants respectfully submit that the Examiner is using the '764 patent as a prior art to the instant claims, which is improper, as stated in *re Vogel* above. The Examiner may in certain instances use the disclosure of a cited patent in an obviousness-type double patenting rejection as a dictionary to learn the meaning of a term in a claim. However, the Examiner cannot go beyond the use of the patent disclosure as a dictionary for terms in a claim requiring additional clarification. Applicants respectfully submit that the claims of the '764 patent are clear on their face and do not require the Examiner's examination of the specification of the '764 patent. If such use of the '764 patent specification is required by the Examiner applicants respectfully request the Examiner identify with clarity and precision what terms of the claims in the '764 patent the Examiner is clarifying from the specification of the '764 patent. The Examiner point to the lists of various salts in the '764 patent to reject the claims of the present application. Applicants respectfully submit that this is an improper use of the patent disclosure of the '764 patent in the present rejection.

The Examiner is required to provide the necessary motivation based upon the art and the claims of the '764 patent not upon the patent disclosure of the '764 patent. The Examiner is using an obvious to try standard by asserting that the disclosure of salts in the '764 patent makes it obvious to make additional salts. More is required. The Examiner needs to point to a motivation or suggestion in the art that suggests the compounds of the claimed invention. The Examiner has not done so. The Examiner has failed to provide

reasons why one of ordinary skill in the art would concluded that the invention in the instant application is an obvious variation of the invention defined in the claims of the '764 patent. Why would one of ordinary skill in the art select the particular salts claimed in the instant application based upon the claims of the '764 patent? Applicants respectfully submit that those of ordinary skill in the art have a multitude of choices based upon the claims of the '764 patent. Why would one make this particular compound from a large list of compounds claimed and furthermore why would one make particular salts claimed in the instant application based upon the patent claims of the '764 patent? The Examiner has merely gone to the specification of the '764 patent to match the salts of the claimed invention to various salts disclosed in the '764 patent specification. No rhyme or reason exists for the Examiner's selection of some salts and non-selection of a large number of additionally disclosed salts.

Applicants' respectfully submit that the Examiner has accessed information in the '764 patent disclosure which is not properly citable against the claims of the present invention. As the Court in *Eli Lilly and Co. v. Barr Laboratories, Inc.* 251 F.3d 955, 973 (Fed. Cir. 2001) explained "it must always be carefully observed that the appellant's patent is not 'prior art' under section 102 or 103 of the 1952 Patent Act" citing *In re Boylan*, 55 C.C.P.A. 1041, 392 F.2d 1017, 1018, n. 1, 157 U.S.P.Q. 370, 371 n. 1 (CCPA 1968). The Examiner has gone beyond the use of the specification for use as a dictionary to learn the meaning of terms in the claims: the meaning of the terms of the claims is perfectly clear on their face without further explanation. As noted in *Eli Lilly* the cited patent is not prior art to the application under examination. The Examiner provided applicants with no explanation why one of ordinary skill in the art would be motivated to make the claimed salts based upon the claims of the '764 patent.

The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof. *E.g., In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985). Applicants respectfully submit that issuance of the claims of the instant application will not result in a time-wise extension of a patent for the same invention. The claims of the instant application are patentable distinct from those of the '764 patent. The compounds claimed in the instant application are distinct from those claimed in the '764 patent claims. Accordingly,

applicants are not receiving an extension of the claimed subject matter in the '764 patent by issuance of the claims of the instant application.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claim 1-37 under obviousness-type-double patenting in view of the claims of the '764 patent. If the Examiner maintains her rejection of the claims of the subject application, applicants respectfully request that she inform applicants with precision where the motivation or suggestion exists in the art to arrive at the claimed invention in the absence of the specification of the '764 patent.

CONCLUSION

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and her rejections set forth in the October 3, 2001 Office Action and earnestly solicit allowance of the claims pending in the subject application. Applicants' undersigned attorney may be reached at the phone number listed below if the Examiner believes that this will help advance prosecution and allowance of the subject application.

Date: Feb 3, 2003

Patent Department, 5th Floor
150 East 42nd Street
New York, NY 10017-5755
(212) 733-1038

Respectfully submitted,

Adrian G. Looney
Adrian G. Looney
Attorney for Applicant
Reg. No. 41,406